manufacturing facility. Colligan is relied upon as teaching the concept of build-to-order manufacturing. Thus, according to the examiner, combining Duffin and Colligan results in the claimed invention. Further, the examiner contends, without support therefor, that it would have been obvious to one having ordinary skill in the art "to have modified...Duffin to include the concept of a customized build-to-order software image to a computer system taught by Colligan in order to fit customers needs."

B. The Obviousness Rejection Applies An Incorrect Legal Standard

The controlling statutory provision of 35 USC §103 requires, as noted on page 4 of the office action, that the differences between the subject matter sought to be patented and the prior art are such that the subject matter "*as a whole would have been obvious*" to a person having ordinary skill in the art. The legal standard applied in the rejection however only finds that it would have been obvious to modify Duffin to include build-to-order software. Thus, the rejection applies an incorrect legal standard. Even if Duffin could be modified to include a build-to-order software feature, that fact nevertheless does not meet the requirement that it would have been obvious to make the claimed combination. For such a finding, there must be some suggestion or motivation for combining the references. Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 50 U.S.P.Q.2d 1161 (Fed. Cir. 1999); In re Dembiczak, 175 F.3d 994, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999). Nowhere does the rejection identify any suggestion to combine the references. The rejection only finds that Duffin could be modified in accordance with Colligan. The Federal Circuit in In re Dembiczak reversed the Board's decision of obviousness for a failure, as here, to cite specific information in the prior art that would suggest the combination of the prior art references. Id. at 1000. Absent such a finding,

a decision of obviousness cannot stand as a matter of law. Id. Thus, the stated rejection of claims 1-7 is in error.

C. The Combination of Duffin and Colligan Fails to Result in the Claimed Subject Matter

Duffin does in fact **not** include a programmer for the implanted medical device. In fact, a distinction of Duffin and an object of its teachings concerns the absence of a programmer. As pointed out in Duffin, the prior art systems had the patient within short range of a programmer. See column 3, lines 59-66. What Duffin sought to solve was the situation where the patient is out of range of the programmer. See column 3, line 67 to column 4, line 4. Item 20 in Duffin is clearly identified as a patient communications control device (col. 7, lines 22-27) and is basically just a repeater to relay communications to and from the remote base station. Accordingly, the combination of Duffin and Colligan fails to result in the claimed subject matter of claims 1-7.

Colligan is characterized as disclosing a "build-to-order" CD ROM. However, Colligan does not disclose a manufacturing facility or process. The CD ROM is custom programmed to permit a user to restore a computer system to a "factory new" software condition. Accordingly, Colligan does not disclose a "build-to-order" manufacturing facility. Thus, the combination of Duffin and Colligan fails to result in the claimed subject matter of claims 1-7.

D. Miscellaneous

1. Provisional Double Patenting Rejection

Claims 1-3 and 5-7 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting relative to co-pending application serial

no. 09/775,281 in view of Colligan (U.S. Patent No. 6,298,443). Applicant will address this rejection when and if it is ultimately made on a non-provisional basis.

2. Drawing Objection

The drawings were objected to because the reference character "60" is shown in both Fig. 2 and Fig. 3 in relation to two different structures. Applicant proposes to correct the drawing by changing numeral "60" in Fig. 3 to the numeral "63." Attached is a revised Fig. 3 with the corrections marked in red.

E. Conclusion

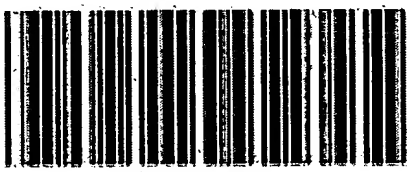
In consideration of the amendments to the claims and the remarks presented herein, Applicant submits that all pending claims are now in condition for allowance and requests that a notice of allowance issue in due course.

Respectfully submitted,

Date: January 14, 2003

By: 

Girma Wolde-Michael
Reg. No. 36,724
Telephone: (763) 514-6402



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**MARKED-UP VERSION OF CHANGES MADE**

IN THE SPECIFICATION:

At page 15, line 1 to page 16, line 19, rewrite the paragraphs as follows:

FIG. 3 is a block diagram of a system in which the invention is practiced. The major components of the system include patient 12, programmer 20, and Information Network [60] 63. Patient 12 may have multiple implants, for example, an implanted bradycardia type pacemaker 10 with and an implanted ICD 15 that has just been implanted. Confining our attention to ICD 15, we note that this device communicates through RF link 57 to the programmer, specifically to wireless interface 51. Data, such as factory-programmed parameters and so on, are forwarded to system controller 52. Under a physician's direction/prescription, these parameters may be altered and downloaded from system controller 52 to ICD 15 via RF wireless interface 51.

Continuing with FIG. 3 and more to the point of its relation to the present invention, we see that the same data as well as the device's model number, serial number, date of implant, and so on are conveyed to system interface 53. At this juncture, the data may be stored or transmitted/telemetered immediately. The time of transmission is completely dependent on whether the programmer is or is not connected to phone link 56 or satellite link 55 at the time of implant. Assuming that one of these connections is made at some time during the day, the data from Internet interface 53 is uplinked to the Internet via phone line modem connection 56 or telemetric satellite link 55 using data encryption technology for a secure transmission as substantially described in filed application No. 09/431,881, *Method and Apparatus to Secure Data Transfer from Medical Device Systems*, filed November 2, 1999, by Nichols and incorporated herein by reference. Upon reaching Information Network [60] 63, these data are incorporated into the data file containing the complete information relating to the implanting institution, for billing purposes and other uses. These same data are also forwarded to that portion of the network computer related to new build orders for manufacturing, which relates to FIG. 4.

Turning our attention now to FIG. 4, we see the various steps used during the manufacturing process to ensure that the recently implanted ICD (using the example

mentioned above) is replaced as quickly as possible. Once the fact that an implant has taken place at a particular institution has occurred and is available in the Information Network [60] 63 (see FIG. 3), that same network, which is constantly monitoring whether a device is to be built as a replacement 70. If not, then the system returns to its monitoring function 72. If such a replacement is required, then the order to build is downloaded to the manufacturing database 74. At the same time, the database enquires whether there are any common requirements needed to manufacture the product 74. If so, then the database will download all pertinent software relative to the implanted device to the automated manufacturing line. Meanwhile, the database is examined to determine if there are any custom specifications required for this replacement 98. If so, the database retrieves any custom software 100, which will then be downloaded into the device's firmware (ROM) during the building of the device 84. The standard data set will include the device type, model number, serial number, name of the implanting physician, the name of the sales representative, and the name of the implanting institution. The customized data set might include (though not limited to), for example, the following: specific functions and/or features, a patient warning alarm, a voice alert in the patient's own language, customized shipping parameters, shipping labels, patient's name and identification number, name of the implanting institution and physician, scheduled date of implant and/or the location where that implant is to take place (e.g., Operating Room No. 3), as well as the institution's inventory management system label. All these data, when received, will automatically initiate a "build-to-order" replenishment to match and replace the customized device(s) implanted at that institution.

At page 20, line 1, replace the Abstract with the following:

**ABSTRACT OF THE INVENTION**

A medical device production and supply information management system [synchronous with manufacturing, planning and scheduling, product consumption forecast and component purchase to enable] for just-in-time inventory control at the manufacturing facility, vendor stocks, material/product tracking, distribution and shipping management, to thereby reduce inventory at all points in the

product manufacturing distribution/delivery chain. The system is implemented using a preferably Web-enabled information network and data communication with a programmer. The programmer provides access to product information, specification and related data for implanted medical devices from which build-to-order or build-to-replenish commands are issued to the manufacturing center. The system is interactive within the information management system that is integrally and seamlessly connected with patients, hospitals, sales offices and related consumption hubs, including manufacturing facilities. [One aspect of the present invention includes a data base containing the information management system, that may download all pertinent software relative to the implanted device to an automated manufacturing line. Procedurally, the database is examined to determined if there are any custom specifications required for the build-to-replenish or build-to-order. In the event there are custom requirements, the database retrieves any custom software which is then downloaded into the device's firmware, during the build-to-replenish or build-to-order. A standard data set will include the device type, model number, serial number, name of the implanting physician, the name of the sales representative and the name of the implanting institution. A customized data set may include, for example, specific functions and/or features, a patient warning alarm, a voice alert in the patient's own language, customized shipping parameters, shipping labels, patient's name and identification number, scheduled date of implant, and/or the location where the implant is to take place, as well as a sufficient inventory management system level. All this data, when received, will automatically initiate a build-to-order replenishment to match and replace the customized device implanted at that institution. Once an order is made, the manufacturing data base will determine whether all components are required to complete the order available at the factory site located nearest the implanting institution. In the event components are not available, the manufacturing database issues an order to the component supplier. In this manner, the invention enables management of inventory levels of medical devices through the interacting information management system by timely and accurately sharing information across the various hubs, thereby

ensuring manufacturing efficiency and cost control throughout the chain of production and supply.]